

Applicant : Eng Shi ONG
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REMARKS

Claims 1-20 are pending in this application. By this Amendment, Applicant has amended claim 7-8. The amended claims 7 and 8 are well supported by the specifications as filed. There is no issue of new matter. Accordingly, applicant respectfully requests the entry of this Amendment. Upon entry, claims 1-20 will be pending and under examination.

New matter objection under 35 USC 132(a)

The Examiner has objected to applicant's amending the upper limit of the pressure range from 30 to 25 bars; and deletion of preferred method step "while the pressure ranges from about 10 - 25 bars" embodied in Claim 4 deleted in applicant's Response of August 18, 2006 on the ground of new matter being introduced into the disclosure as a result of such amendment and deletion.

In response, applicant merely narrowed down the range of pressure claimed, i.e. from "10 - 30 bars" to "10 - 25 bars" in amending Claim 1. Certainly the range of 10 - 25 falls within, and is fully supported by, the original range of 10 - 30. There is no new matter being introduced as a result.

As a result of the narrowed down range, original Claim 4 became redundant; hence, applicant proposed to delete it.

Put in another way, applicant has merely combined the preferred feature of applicant's invention as embodied in Claim 4 into Claim 1 and makes that feature essential. Applicant has therefore delimited applicant's invention to one particular preferred embodiment having a narrower pressure range. Certainly no new matter was introduced as a result.

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If the pressure originally claimed and disclosed is a discrete value such as "at 30 bars", instead of a range, then applicant might have to justify the amended value "at 25 bars".

Accordingly, applicant does not propose any further amendment to Claim 1.

Objections under 37 CFR 1.75(c) for improper dependency

The Examiner has raised objection against Claims 7 - 8, and Claims 13 - 14 under 37 CFR 1.75(c) "as being of improper dependent form for failing to further limit the subject matter of a previous claim."

Applicant points out that 37 CFR 1.75(c) merely requires a claim that is "presented in dependent form" [to] "referring back to and further limiting another claim" without specifying if that limitation is in respect of the body or preamble of the claim.

Applicant's perusal of the other provisions of 37 CFR 1.75 also did not find any requirement of dependency to be limited to the body of a claim.

In Claim 7, applicant has limited the "sample" of Claim 1's preamble to comprise a dispersant. In Claim 8, applicant has further limited that dispersant of Claim 7 to be selected from "sand and glass beads".

Accordingly, applicant's dependency indeed narrows or further delimits the scope of method Claim 1 in Claim 7, and by extension, Claim 7 in Claim 8 albeit the limited feature is comprised in the preamble of the claims.

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Applicant nevertheless voluntarily amends Claim 7 to be independent so as to better define the delimitation of the "sample" to "further include" dispersant in order to avoid the possibility of the dispersant being interpreted as substituting the "sample."

Claim 8 is presently amended to eliminate the dependency issue present in the original PCT application.

For the reasons given in previous paragraphs, applicant does not propose any amendments to Claims 13 and 14 as the delimitation of the "sample" and "analytes" of the respective claims' preamble constitute proper further limitation of the scope of the respective claims as a whole under 37 CFR 1.75.

Accordingly, in view of the foregoing, applicant maintains all issues of dependency has been addressed.

Rejection under 35 USC §102 (anticipation)

Quoting 35 USC §102(e) the Examiner has cited U.S. Patent No. 6,524,628 (Wai), which has previously been cited in the First Office Action, as anticipating applicant's present invention, in particular Claims 1 - 9, 11, 13 and 15 - 17.

Applicant has duly noted the provisions of 35 USC §102(e) and wish to assure the Examiner that applicant fully acknowledges Wai to be a properly cited prior art in view of its publication date and applicant's international filing date ever since it was first cited in the Office Action of April 17, 2006; otherwise, applicant has attempted to qualify Wai as a "P" or "E" citation category under the PCT system in applicant's First Response.

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Applicant agrees with the Examiner's observation that Wai discloses a method for water mediated extraction of analytes from a sample comprising contacting an analyte-containing sample with water below 100°C and at a regulated pressure from 25 - 100 bar.

Applicant, however, points out, as applicant did in the First Response, that applicant's Claim 1 is distinguishable from Wai in respect of the regulated pressure, which is below that of Wai. Perusing the entire specification of Wai fails to find any teaching that would suggest that Wai's method works below 25 bar.

Upon applicant's perusal of the entire specification, all the occurrences of pressure value mentioned in Wai are listed in the following:

Abstract, bibliographic page:

"between about 25 atm and about 1000 atm"

This has no suggestion that it works at less than 25 bar.

Figure 4, and the corresponding description at column 3 lines 26 - 30 (Brief Description of the Drawings), and column 10 lines 48 - 55 (Detailed Description/ Examples) wherein is stated that

"A "threshold" pressure was observed for the extractions of terpene trilactones from the leaf samples. Below the threshold pressure, either the solvent could not flow through the sample bed due either to the (1) low porosity of the packed leaf powders or (2) slow diffusion of the solvent through the pressure was approximately 50 atm (see FIG. 4)."

This all does not teach nor suggest that Wai's method would work below 25 bar.

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Column 1 lines 54 - 55:

"a pressure between about 25 atm and about 1000 atm, more typically from about 50 atm to about 200 atm."

There is no suggestion that Wai's method works below 25 atm.

Column 2 lines 63 - 64:

"a pressure of at least about 50 atm (e.g., about 100 atm)".

This represents a threshold higher than 25 atm.

Column 4 lines 9 - 11:

"Pressures of generally greater than 25, typically greater than about 50 atm and up to about 1000 atm are useful."

There is no suggestion here that Wai's method works at below 25 atm.

Column 8 lines 55 - 58:

"For most experiments, an aqueous composition at 100 atm of pressure was first mixed ..."

This indicates that Wai's method was practiced at 100 atm, which is the maximal recovery rate, consistent with the results of Figure 4.

Column 10 line 10:

"Temperature: The pressure was set at 100 atm, ..."

This is the pressure employed for Gingko biloba extraction results, one of the two plant materials disclosed; the other being grape seed.

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Column 10 line 64 - column 11 line 5:

In the experiments hereafter, 100 atm pressure was used for all the extractions. Pressures lower than about 200 atm, and preferably pressures from about 50 atm to about 100 atm, are preferred because extraction equipment that operates at these pressures is less expensives and more reliable. In general, pressure in the range from about 25 atm to about 1000 atm are useful, with pressures in the range from about 50 atm to about 200 atm providing the best extraction results.

It would appear that, the supported range is actually 50 to about 100 or 200 atm and the broader range of 25 to 1000 atm is made speculatively, particularly the lower range of 25 to 50, and above 200 atm since no results have been presented to support these extreme portions of the broad range.

Column 12 line 66 - 67:

"In summary, quantitative extraction of gingkolides and bilobalide at room temperature and 100 atm pressure ..."

This provides the summary of the pressure employed for extraction results of Gingko biloba.

Column 14 line 65 - 67:

"The grape seed powder was exposed at room temperature and a pressure of 100 atm ..."

This indicates that this second plant material was also subjected to 100 atm of pressure in Wai's extraction method.

In the Claims, it should be noted that the lower range of 25 - 50 atm is not claimed in any of the 68 claims granted. Instead, the broad general range of 50 - 1000 atm is claimed in independent

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Claims 1 and 43, while the preferred, narrower range of 50 - 200 atm is claimed in independent Claims 31 and 53.

In concluding, applicant submits that the best mode pressure of Wai is 100 atm while the disclosed and supported range is 50 - 200 atm. The lower range of 25 - 50 mentioned is thus unsupported and is at best speculative. In any event, there is no disclosure nor suggestion whatsoever that Wai method may work at below 25 atm. With the "threshold" established at 50 atm, a skilled person reading upon Wai would be discouraged from practicing the method in the range of 25 - 50 atm and certainly would not be motivated to venture out of the range to practice the extraction method at below 25 atm.

While applicant's agree with the Examiner's findings that Wai has also disclosed a number of other features of applicant's invention such as water below 100°C; water containing organic solvent such as ethanol; water containing sand as flow dispersant; contacting time of about 15 minutes; flow rate of contact at about 1 ml/min; and the analytes may be detected using gas chromatography *loco citato* in the Office Action on page 4, applicant submits that by virtue of the novelty of the pressure feature asserted above, applicant's claims pertaining to these other features as cited by the Examiner, i.e. Claims 2 - 9, 11, 13 and 15 - 17, are novel as well. Accordingly, applicant humbly requests reconsideration by the Examiner on this important pressure feature to overcome the present rejection under 35 USC §102.

Rejection under 35 USC §103 (obviousness)

The Examiner has maintained that U.S. Patent No. 4,176,228 (Hartung) renders applicant's invention obvious in respect of Claims 1, 2 and 14. In particular, the single sentence in Hartung

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stating that "Pressures above atmospheric may be used to facilitate the extraction process" is being harped upon as rendering obvious applicant's pressure of 10 - 25 bars.

It should be noted that Hartung's disclosure is solely for the extraction of glycyrrhizin from licorice root. There is no mention of any other plant materials as the source of extracts or analytes, nor is mentioned any other types of extracts or analytes apart from glycyrrhizin. There is also no suggestion by Hartung that its method would work on plant materials or for extracting other extracts apart from glycyrrhizin which is available in relatively larger fraction of the sample (i.e. licorice root).

From the discussion of the prior art and detailed description in Hartung, a skilled person would understand from the disclosure that the method is peculiar to extraction of glycyrrhizin from licorice root, rather than extracting analytes in small amounts or portions from a sample. In fact, applicant's perusal of the citations mentioned in the Background discussion of Hartung (namely US-762,032; US-1,389,663; US-1,849,569; US-2,058,019; US-764,896 and US-3,851,073) indicates that they are all directed to extracting glycyrrhizin from licorice, thus further reinforcing a skilled person's preception of Hartung as applicable only to licorice.

It should be noted that the role of pressure was not discussed at all in Hartung apart from the sole non-committal statement quoted in paragraph 5.1 above. In fact, it is applicant's opinion that this sole reference to pressure means that elevated pressure is not essential to Hartung's process; and if at all employed the method would not be hindered or adversely altered by elevated pressure.

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In light of other corroborated statements indicating "no special conditions" are necessary apart from the respective preferred temperatures for acidification (column 3 line 54 - 57) and alkalification (column 4 lines 21 - 24), a skilled person reading Hartung would thus not be motivated to employ elevated pressure for the process.

In line with Occam's Razor doctrine of inquisitive parsimony, an inquisitive skilled person would be motivated to repeat Hartung's method with the minimal set of conditions and requirements which would certainly exclude elevated pressure which is deemed unnecessary in the absence of any specific figures or values.

Alternatively, without any specific figures or suggestion of the elevated pressure, a skilled person might handily experiment with the common pressure cooker which normally offers between 5 lbs ("low" setting) to 15 lbs per inch ("high" setting) above the atmospheric pressure of 14.7 lbs/in², which pressure value attainable is thus at a maximum value of about 2 atm. It is applicant's contention that at the very unlikely event a skilled person would be motivated to employ the non-committal "elevated pressure", he/she would employ up to 2 atm or lower digits of atmospheric pressure whereas applicant's invention calls for pressures of at least 10 atm which cannot be attained without sufficient notice and preparation.

With regard to the Examiner's views that performing extraction processes at elevated pressure would be a "well-known and expected result" of more efficient extraction, applicant wishes to point out that this may not always be the case, especially with the extraction of biological materials, which are generally pressure-labile. One may equally argue that such general knowledge or "well-known and expected result" of elevated pressure would

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conversely be applied to discourage use of elevated pressure which is well-known and expected to damage, denature, inactivate or decompose the intended biological extract or analyte.

Accordingly, applicant submits that a skilled person reading Hartung alone in combination with his/her conventional knowledge and expected result would not have carried out the method at applicant's elevated pressure of 10 - 25 atm.

In respect of the Examiner's rejection against Claims 1 - 9, 11 and 13 - 17 as render obvious by Hartung in view of Wai, applicant reiterates that a skilled person combining the teachings of both citations would at best be led to conduct Hartung's licorice extraction process at Wai's pressure of 50 - 100 atm.

In respect of the Examiner's obviousness rejection against Claims 10 and 12 in respect of contacting time and ethanol concentration light of Wai, applicant reiterates that applicant's essential feature distinguishing Wai is the range of pressure of 10 - 25 atm in which applicant's method is conducted, as submitted above. With applicant's said pressure range submitted presently as novel and inventive, in combination with preferred features of the contacting time and solvent concentration as defined in Claims 10 and 12 respectively, applicant's said claims are still patentable over Wai.

Obviousness Rejection: new citation WO 99/22868

The Examiner has raised a new citation, WO 99/22868 (Laugharn) as rendering Claims 18 - 20 obvious over Wai in view of International Patent Publication No. WO 99/22868 (Laugharn) in respect of the use of surfactant or detergent for eluting extracts from plant materials.

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While acknowledging that surfactants and detergents are commonly used in the art for extraction of large molecules such as proteins by eluting them out of biological complexes or materials, applicant wishes to point out that in reference cited by the Examiner in Laugharn (page 8 lines 7 - 15), the use of detergent is for the purpose of permeabilizing and ultimately lysing the cells (page 8 lines 1 - 2). It should be noted that Laugharn's method is mainly to lyse cells and extract their nucleic acids. For plant cells which membrane is protected by cellulose walls, lysis may not happen.

The second occurrence of detergent use in Laugharn cited by the Examiner at the paragraph bridging pages 28 - 29, applicant again points out that detergent is proposed to be used as one of the chemical methods of lysing cells.

By lysing cells, applicant would like to point out, is to undo the contents of the cells into the medium so that the nucleic acids (as well as other components of the cytoplasm) becomes available for extraction. It is only a prelude to actual extraction. Laugharn's actual extraction equivalent (which is purification) step involves electrophoresis or electro-osmotic capillary action provided by its electrode-array system.

In addition to the major difference in the role of detergent, applicant would also point out that Claims 18 - 20 are dependent on Claim 1, whether directly or indirectly. They are thus defined to include the feature of pressure at 10 - 25 bar, which applicant has submitted at length above, to be novel and inventive. Accordingly, applicant submits that Claims 18 - 20 are not rendered obvious by Wai in view of Langharn.

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CONCLUSION

Applicant respectfully maintain that all the grounds of rejections raised in the November 13, 2006 Office Action have been addressed and earnestly urge the Examiner to render favorable action for the claimed invention.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below. If any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

Albert Wai-Kit Chan

Albert Wai-Kit Chan
Registration No. 36,479
Attorney for Applicant
Law Offices of
Albert Wai-Kit Chan, LLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, New York 11357
Tel: (718) 799-1000
Fax: (718) 357-8615
E-mail: chank@kitchanlaw.com